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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/445,614 | 12/08/99 | BONNERT T | T1481 |

HM12/0309

PATENT DEPARTMENT
MERCK & CO INC
P.O. BOX 2000
RAHWAY NJ 07065-0907

| EXAMINER | |
|---|---|
| BRANNOCK,M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1646 | 8 |

**DATE MAILED:** 03/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademark**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/445,614 | Bonnert |
| **Examiner** | **Group Art Unit** |
| Michael Brannock, Ph.D. | 1646 |

☒ Responsive to communication(s) filed on *Dec 8, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**

☒ Claim(s) *1-3, 5-10, 12, 13, 15, and 16* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-3, 5-10, 12, 13, 15, and 16* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ NOTICE TO COMPLY WITH SEQUENCE RULES

***--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---***

## DETAILED ACTION

1. Claims 1-3, 5-10, 12, 13, 15, and 16 are pending. Applicant is notified that the amendments put forth in Paper 6, 12/08/00 have been entered in full.

### *Sequence Rules Compliance*

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825, within the statutory period set forth for response in this Office Action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

### *Election/Restriction*

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 5, 7-9, drawn to polynucleotides, vectors, host cells , and methods of producing a polypeptide, classified in class 536, subclass 23.5.

II. Claim 6, drawn to a method for detecting altered expression of a polynucleotide, classified in class 435, subclass 6.

III. Claims 10 and 12, drawn to polypeptides, classified in class 530, subclass 350.

IV. Claim 13, drawn to antibodies, classified in class 530, subclass 388.22.

V. Claim 15, drawn to methods of detecting a polypeptide, classified in class 435, subclass 7.2.

VI. Claim 16, drawn to method of identifying binding partners of a polypeptide, classified in class 436, subclass 501.

4. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, III and IV are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group III can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group III, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group III can be used in materially different methods other than to make the antibody of Group IV, such as in therapeutic or diagnostic methods (e.g., in

screening). Finally, although the antibody of Group IV can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups II, V, and VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group II requires a method of DNA hybridization, which is not required by any of the other groups. Group V requires a method for detecting protein with an antibody, which is not required by any of the other groups. Group VI requires a ligand binding assay which is not required by any of the other groups.

The polynucleotides of Group I are related to the methods of Groups II and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I are patentably distinct from each of the methods of Groups II and VI because the polynucleotides of Group I can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups II and VI are materially and functionally distinct from the others. Furthermore, the polynucleotides of Group

II and the methods of Group V are patentably distinct because one is not required for the use of the other.

The polypeptides of Group III are related to the methods of Groups V and VI as product and process of use. In the instant case the polypeptides of Group III are patentably distinct from each of the methods of Groups V and VI because the polypeptides of Group III can be used in ways that are materially and functionally different than each of the methods because, as discussed above, each of the methods of Groups V and VI are materially and functionally distinct from the others. Furthermore, the polypeptides of Group III and the method of Group II are patentably distinct because one is not required for the use of the other.

The antibodies of Group IV are related to the method of Group V as product and process of use. In the instant case the antibodies of Group IV are patentably distinct from the method of Group V because the antibodies of Group IV can be used in ways that are materially and functionally different the method of Group V, e.g. the antibodies can be used to purify the polypeptide of Group III. Furthermore, the antibodies of Group IV and the methods of Groups II and VI are patentably distinct because one is not required for the use of the other.

Therefore, a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

March 8, 2001

Primary Examiner